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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,257	03/21/2001	Nancy D. Hanson	180.00030102	6204

26813 7590 12/11/2003

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EXAMINER	
LU, FRANK WEI MIN	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 12/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

SM.

Office Action Summary	Application No.	Applicant(s)	
	09/814,257	HANSON ET AL.	
	Examiner	Art Unit	
	Frank W Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-17,39-44,47-49 and 51-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *12-16 and 51* is/are allowed.

6)☒ Claim(s) *17,39-44,47-49,and 52-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10/2003* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. Applicant's response to the office action filed on September 22, 2003 has been entered. The claims pending in this application are claims 12-17, 39-44, 47-49, and 51-54. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn in view of amendment filed on September 22, 2003.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 17, 39-44, 47, 48, and 52-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 17 and 52-54 are rejected as vague and indefinite in view of the phrase "wherein one primer of the pair is complements to at least a portion of the beta-lactamase nucleic acid in the sense strand and the other primer of each pair is complementary to at least a portion of the beta-lactamase nucleic acid in the antisense stand" because it is unclear that "the pair" and "each pair" in the phrase are directed to the same pair of oligonucleotide primer or not. If "the pair" and "each pair" in this phrase are directed to the same pair of oligonucleotide primers, the examiner suggests applicant to change "each pair" to "the pair" in order to make the first part of the phrase corresponds to the second part of the phrase.

5. Claims 17 and 52-54 are rejected as vague and indefinite in view of the phrase " wherein each extension product after separation from the beta-lactamase nucleic acid serves as a template for the synthesis of an extension product for the other primer of each pair" because it is unclear what the phrase means. Since it is known that, during the PCR, each extension product after separation from its complementary strand (its template) serves as a template for the synthesis of another extension product in later cycles using a primer that is complementary to each extension product, the phrase "the other primer of each pair" in claims 17 and 52-54 are not clear enough for one skilled artisan to understand claimed invention. The examiner suggests applicant to change the phrase "for the other primer of each pairs" to "using a primer that is complementary to each extension product".

Response to Arguments

In page 16, fourth paragraph of applicant's remarks, applicant indicates that "[A]pplicants respectfully assert that in view of the comments herein, in addition to independent claims 17, 52, 53, and dependent claim 44, claims 39-43, 47, and 48, directly or ultimately dependent on claim 17, are also not indefinite under 35 U.S.C. § 112. second paragraph.".

The argument has been fully considered but it is not persuasive toward the withdrawal of the rejection because applicant has not indicated why the rejections under 35 U.S.C. § 112 in previous office action are not correct. Since the phrase "each pair" in claims 17, 52, and 53 means that the claims have at least two pairs of primers which do not correspond to the first method step of the claims wherein the claims only have a pair of oligonucleotide primers. Note that the examiner has withdrawn the rejection on claim 44 after applicant amends claim 44.

6. Claims 17 and 54 are rejected as vague and indefinite in view of "providing a pair of oligonucleotide primers specific for nucleic acid characteristic of the OXA family of beta-lactamase enzymes, the enzyme is found in a Gram-negative bacterium selected from the group of *Enterbacter cloacae, Cltrobacter freundii, Serratia marcescens, Providencia spp., Proteus mirabills, Yersinia enterocolitica*, and combinations thereof" because the phrase "the enzyme" lack an antecedent basis. The examiner suggests that applicant changes "the enzyme" to "the enzymes" in order to overcome the rejection. Please clarify.

Claim Rejections - 35 U.S.C. § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 17, 39, 41, 43, 47, and 54 are rejected under 35 U.S.C. 102(a) as being anticipated by Vahaboglu *et al.*, (J. Clin. Microbiology, 36, 827-829, March 1998).

Vahaboglu *et al.*, teach the detection and identification of OXA-10-derived ceftazidime-hydrolyzing extended-spectrum β-lactamases in *Pseudomonas aeruginosa* isolates from clinical samples. PCR was designed to amplify a 720 bp fragment of beta lactamases of OXA-7, -13, -10, -17, -11, -14 and -16 genes with a sense primer OPR1 and an antisense primers OPR2 of beta

lactamase OXA-10 and PCR products from beta lactamase OXA-10, -17, -11, -14 and -16 were analyzed by gel electrophoresis in order to differentiate different OXA subtypes (see pages 827 and 828 and Figure 1)

Regrading claim 17, since Vahaboglu *et al.*, teach to amplify beta lactamases of OXA-7, -13, -10, -17, -11, -14 and -16 genes with a sense primer OPR1 and an antisense primers OPR2 of beta lactamase OXA-10 and analyze PCR products from beta lactamases of OXA-10, -17, -11, -14 and -16 by gel electrophoresis in order to differentiate different OXA subtypes, Vahaboglu *et al.*, disclose all method steps recited in claim 17. Although claim 17 requires a pair of oligonucleotide primers specific for nucleic acid characteristic of the OXA family of beta-lactamase enzymes wherein the enzymes are found in a Gram-negative bacterium selected from the group of *Enterbacter cloacae, Cltrobacter freundii, Serratia marcescens, Escherichia coil, Providencia spp., Proteus mirabills, Yersinia enterocolitica*, and combinations thereof excluding OXA-1 and analyzing the separated amplified products for a region characteristic of a beta-lactamse found in a Gram-negative bacterium selected from the group of *Enterbacter cloacae, Cltrobacter freundii, Serratia marcescens, Escherichia coil, Providencia spp., Proteus mirabills,* and *Yersinia enterocolitica*, the claim does not limit that the nucleic acid used for amplification is a nucleic acid sequence from *Enterbacter cloacae, Cltrobacter freundii, Serratia marcescens, Escherichia coil, Providencia spp., Proteus mirabills,* and *Yersinia enterocolitica.* The claim merely requires a nucleic acid "characteristic" of the OXA family. Vahaboglu *et al.*, teach detection of the OXA and therefore teaches detection of nucleic acid "characteristic" of the OXA family as claimed.

Regarding claims 39, 41, 43, and 47, since OXA-7, -13, -10, -17, -11, -14 and -16 beta lactamase genes from *Pseudomonas aeruginosa* isolates from clinical samples encode beta-lactamases while OXA-2, 3, 5-7, and 9-15 beta-lactamases recited in claims 39, 41, 43, and 47 encode beta-lactamases, OXA-7, -13, -10, -17, -11, -14 and -16 beta lactamase genes from *Pseudomonas aeruginosa* isolates are considered to have characteristic of OXA-2, 3, 5-7, and 9-15 beta-lactamases. Therefore, claims 39, 41, 43, and 47 are anticipated by Vahaboglu *et al.*.

Regrading claim 54, since Vahaboglu *et al.*, teach to amplify beta lactamases of OXA-7, -13, -10, -17, -11, -14 and -16 genes with a sense primer OPR1 and an antisense primers OPR2 of beta lactamase OXA-10 and analyze PCR products from beta lactamases of OXA-10, -17, -11, -14 and -16 by gel electrophoresis in order to differentiate different OXA subtypes, Vahaboglu *et al.*, disclose all method steps recited in claim 17. Although claim 17 requires a pair of oligonucleotide primers specific for nucleic acid characteristic of the OXA family of beta-lactamase enzymes wherein the enzymes are found in a Gram-negative bacterium selected from the group of *Enterbacter cloacae, Cltrobacter freundii, Serratia marcescens, Providencia spp., Proteus mirabills, Yersinia enterocolitica*, and combinations thereof and analyzing the separated amplified products for a region characteristic of a beta-lactamse found in a Gram-negative bacterium selected from the group of *Enterbacter cloacae, Cltrobacter freundii, Serratia marcescens, Providencia spp., Proteus mirabills,* and *Yersinia enterocolitica*, the claim does not limit that the nucleic acid used for amplification is a nucleic acid sequence from *Enterbacter cloacae, Cltrobacter freundii, Serratia marcescens, Escherichia coil, Providencia spp., Proteus mirabills,* and *Yersinia enterocolitica.* The claim merely requires a nucleic acid

"characteristic" of the OXA family. Vahaboglu *et al.*, teach detection of the OXA and therefore teaches detection of nucleic acid "characteristic" of the OXA family as claimed.

Therefore, Vahaboglu *et al.*,teach the limitations recited by claims 17, 39, 41, 43, 47, and 54.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vahaboglu *et al.*, (March, 1998) as applied to claims 17, 39, 41, 43, 47, and 54 above, and further in view of Fluit *et al.*, (WO91/08305, published on June 13, 1991).

The teachings of Vahaboglu *et al.*, have been summarized previously, *supra*. Since Vahaboglu *et al.*, teach to amplify beta lactamases of OXA-7, -13, -10, -17, -11, -14 and -16 genes with a sense primer OPR1 and an antisense primers OPR2 of beta lactamase OXA-10 (see pages 827 and 828 and Figure 1) and the claim does not limit that the nucleic acid used for amplification is a nucleic acid sequence from *Enterbacter cloacae, Cltrobacter freundii, Serratia marcescens, Escherichia coil, Providencia spp., Proteus mirabills,* and *Yersinia enterocolitica*, Vahaboglu *et al.*, disclose (a) of the claim. Since Vahaboglu *et al.*, teach to amplify OXA beta lactamases from OXA positive isolates and OXA-negative isolates (see page 828, Figure 1), Vahaboglu *et al.*, disclose (b) of the claim. Since Vahaboglu *et al.*, teach the method for identify OXA beta lactamases by gel electrophoresis of digested PCR products of OXA beta lactamases and DNA sequencing of PCR products of OXA beta lactamases (see page 828), Vahaboglu *et al.*, disclose (c) of the claim.

Vahaboglu *et al.*, do not disclose a bacteria diagnostic kit as recited in the claim.

Fluit *et al.*, do teach a bacteria diagnostic kit (see pages 24 and 25).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have organized the components and method taught by Vahaboglu *et al.*, into a kit because the method for identifying a beta-lactamase in a bacteria sample by analyzing PCR products of the beta-lactamase or sequencing of PCR products of the beta-lactamase was known at that time the inventions were made and the kit format was utilized not only to assemble a variety of different reagents together but ensured the quality and compatibility of the reagents. One having ordinary skill in the art at the time the invention was

made would have been motivated to assemble reagent (s) of biotechnology methods into a kit in order to obtain the above discussed advantages, thus resulting in instant kit recited in claim 49. One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to combine these prior art together because the kit would provide a convenient, efficient, economical way to practice the method of Vahaboglu *et al.*.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Claims 12-16 and 51 are allowed since SEQ ID Nos: 34-43 are free of prior art.

13. Claims 52 and 53 appears to be allowable if applicant can overcome the rejection under 35 USC 112, second paragraph.

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Scoulica *et al.*, Antimicrobial Agents and Chemotherapy, 39, 1379-1382, June 1995.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270 (before January 13, 2004) or 571-272-0746 (after January 13, 2004). The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
December 5, 2003

BJ FORMAN, PH.D.
PRIMARY EXAMINER